

**OKLAHOMA STATE UNIVERSITY  
CENTER FOR HEALTH SCIENCES**

**CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH REGISTRY**

TITLE: \_\_\_\_\_ Disease Research Registry

PRINCIPAL INVESTIGATOR: \_\_\_\_\_

PRINCIPAL INVESTIGATOR'S ADDRESS: \_\_\_\_\_

PRINCIPAL INVESTIGATOR'S TELEPHONE NUMBER: \_\_\_\_\_

CO-INVESTIGATORS: \_\_\_\_\_ Disease Physicians and Research Staff  
(Complete, current listing available upon request)

SOURCE OF SUPPORT: \_\_\_\_\_

What is the purpose of this Research Registry?

Many advancements in medicine have resulted from research involving the collection and analysis of the medical record information of patients with a certain disease or condition. Because you are being seen by the Oklahoma State University-Center for Health Sciences ("OSU-CHS") Center for Study of \_\_\_\_\_ Disease, we are asking for your permission to allow us to place your past, current and future medical record information into a Center for Study of \_\_\_\_\_ Disease Research Registry. By placing the medical record information of many patients such as you into a research registry, researchers will be able to conduct research studies directed at increasing our knowledge about \_\_\_\_\_ disease.

It is anticipated that the Research Registry will assist our investigators in two important ways.

First, it will allow researchers to review and study the medical records of many individuals to answer questions about your disease and its treatment.

Second, it will help researchers identify and recruit patients who are eligible for participation in future research studies. For example, physicians and other researchers associated with the OSU-CHS Center for Study of \_\_\_\_\_ Disease are also frequently involved in research studies directed at evaluating the safety and effectiveness of drugs, devices or procedures for the treatment of \_\_\_\_\_ disease. If you agree to participate in this Research Registry,

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your medical record information will be reviewed by physicians and researchers to determine if you might qualify for various future research studies.

***Who is being asked to participate in this Research Registry?***

All adult patients who are seeking treatment or are being treated at the OSU-CHS Center for Study of \_\_\_\_\_ Disease are being asked to participate in this Research Registry.

***What will my participation in this Research Registry involve?***

If you agree to participate in the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry, your past, current and future medical record information will be placed into the Research Registry. This will permit research studies to be conducted on the medical record information contained within the registry. You are being asked to allow us to contact you if one of our researchers determines, through review of your medical record information contained in the Research Registry, that you are eligible for participation in a future research study directed at the study of \_\_\_\_\_ disease. Please note that if you qualify for any future research studies, you will be asked to sign a separate consent form that outlines in detail the nature of this research study, including its potential risks and benefits.

***What are the possible risks of my participation in the Research Registry?***

There are no risks of physical injury associated with your participation in the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry. Participation in this Research Registry does involve the possible risk that information about your health might become known to individuals outside of the OSU-CHS Center for Study of \_\_\_\_\_ Disease.

We will attempt to preserve your medical record confidentiality by assigning a special research code number to your medical record information stored in the Research Registry, and by removing personal identifiers (for example, your name, social security number, medical record number) from information stored about you in the Research Registry. Information linking the research code number to your name and other personal identifiers will be stored in a separate secure location. Access to any identifiable information about you that is contained within the Research Registry will be limited to investigators associated with the OSU-CHS Center for Study of \_\_\_\_\_ Disease and their research staffs.

***What are the possible benefits of my participation in the Research Registry?***

It is unlikely that you will receive any direct benefit as a result of your participation in the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry.

However, medical record information contained within the Research Registry will be used for research studies directed at improving our knowledge and treatment of \_\_\_\_\_

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disease and this knowledge may benefit patients with \_\_\_\_\_ disease in the future.

***Will I or my insurance provider be charged for my participation in the Research Registry?***

There will be no costs to you or your insurance provider to participate in this Research Registry.

***Will I be paid for my participation in the Research Registry?***

No, you will not receive any payment for participating in this Research Registry.

***Who will know about my participation in this Research Registry?***

Any information from your medical records that is placed into this Research Registry will be kept as confidential (private) as possible. In addition, you will not be identified by name in any publication of the results of research studies involving the use of your medical record information unless you sign a separate authorization form (release) giving your permission.

***What is the nature of my medical record information that will be placed into the Research Registry?***

All of your past, current and future medical record information related to your \_\_\_\_\_ disease will be recorded into the Research Registry. Since medical conditions and treatments not related directly to your \_\_\_\_\_ disease may affect \_\_\_\_\_ disease and/or its treatment, it is likely that all of your existing and future medical record information will be placed in the Research Registry. This information will be collected from your OSU-CHS Center for Study of \_\_\_\_\_ Disease clinic records, hospital records and, if applicable, private physician records.

***Who will have access to my identifiable medical record information contained in the Research Registry?***

Access to your identifiable medical record information contained within this Research Registry will be limited to investigators associated with the OSU-CHS Center for Study of \_\_\_\_\_ Disease and their research staffs. A current, complete listing of these individuals will be provided to you upon your written request.

In addition, authorized representatives of the OSU-CHS Privacy Officer Staff may review information contained within the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry to ensure that the Research Registry adequately protects your privacy.

In unusual cases, the researchers may be required to release your identifiable medical record information from the Research Registry in response to an order from a court of law.

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***For how long will my medical record information continue to be placed in the Research Registry and for how long will this information be used for research purposes?***

We will continue to place your medical record information into the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry until 1) you are no longer living; or 2) you withdraw your permission for participation in the Research Registry.

Your medical record information contained within the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry will be used for research purposes for an indefinite period of time.

***Is my participation in the Research Registry voluntary?***

Your participation in the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry, to include the use of your medical record information for the research purposes described above, is completely voluntary. Whether or not you provide your permission for participation in this Research Registry will have no affect on your current or future medical care at the OSU-CHS, affiliated health care providers, or your current or future relationship with a health care insurance provider. Whether or not you provide your permission for participation in this Research Registry will have no affect on your current or future relationship with the OSU-CHS.

***May I withdraw, at a future date, my consent for participation in this Research Registry?***

You may withdraw, at any time, your consent for participation in the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry, to include the additional collection of your medical record information and its further use for the research purposes described above. However, any research use of your medical record information prior to the date that you formally withdraw your permission will not be destroyed.

To formally withdraw your permission for participation in the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry you should provide a written and dated notice of this decision to the principal investigator of the Research Registry at the address listed on the first page of this consent form.

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**VOLUNTARY CONSENT**

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of my participation in the Research Registry at any time, and that such future questions will be answered by the physicians associated with the OSU-CHS Center for Study of \_\_\_\_\_ Disease or their research staffs. I understand that a copy of this consent form will be given to me.

I understand that any questions which I have about my rights as a participant in the Research Registry will be answered by the Human Participant Protections Advocate of the IRB Office, OSU-CHS (\_\_\_\_-\_\_\_\_-\_\_\_\_).

**By signing below, I agree to participate in the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry.**

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

**CERTIFICATION OF INFORMED CONSENT**

I certify that I have explained the nature and purpose of the OSU-CHS Center for Study of \_\_\_\_\_ Disease Research Registry to the above-named individual, and I have discussed the possible risks and potential benefits of participation in this Research Registry. Any questions the individual has about this Research Registry have been answered, and the physicians and research staff associated with the OSU-CHS Center for Study of \_\_\_\_\_ Disease will be available to address future questions as they arise.

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

Participant's Initials \_\_\_\_\_